DEPARTMENT OF ENVIRONMENTAL QUALITY
WASTE & HAZARDOUS MATERIALS DIVISION
IONIZING RADIATION RULES

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PART 12. SEALED RADIOACTIVE SOURCES IN THE HEALING ARTS

R325.5461. Purpose and scope.

Rule 461. (1) This part establishes radiation safety requirements for persons utilizing sealed sources in the healing arts.

(2) This part applies to all licensees who use sealed sources in the healing arts. In addition to the requirements of this part all licensees are subject to all applicable provisions of the other parts.

[Note: As a result of Executive Order 1996-1, the authority, powers, duties, functions, and responsibilities of the radioactive material registration, licensing, and compliance program were transferred from the Michigan Department of Public Health to the Michigan Department of Environmental Quality.]

INTERSTITIAL, INTRACAVITARY AND SUPERFICIAL APPLICATIONS

R325.5462. Accountability, storage and transit.

Rule 462. (1) Except as otherwise specifically authorized by the department, a licensee shall provide accountability of sealed sources and shall maintain a record of all issues (or receipts) and returns of sealed sources on Form RH-103 or equivalent. A physical inventory shall be made at least every 6 months if sources are stored at the facility between treatments or upon receipt of case lease shipments. Results of the inventory shall be recorded on Form RH-103 or equivalent. Accountability records shall be maintained for inspection as required by rule 245.

(2) When not in use, sealed sources and applicators containing sealed sources shall be kept in a protective enclosure of such material and wall thickness as may be necessary to assure compliance with rules 203, 205, 210 and 211.

(3) Transit of sealed sources within the authorized treatment facility shall be conducted only by persons approved by the radiation protection supervisor and only in such manner as designated in written procedures approved by the department before issuance of a specific license for such use. Transfer of sealed sources outside the authorized treatment facility shall be subject to rule 255 and any specific license conditions.

[Note: As a result of Executive Order 1996-1, the authority, powers, duties, functions, and responsibilities of the radioactive material registration, licensing, and compliance program were transferred from the Michigan Department of Public Health to the Michigan Department of Environmental Quality. Form RH-103 has been renamed EQP-1613.]

R325.5464. Testing sealed sources for leakage and contamination.

Rule 464. (1) All sealed sources with a half-life exceeding 30 days and in any form other than gas shall be tested for leakage, contamination or both before initial use and at intervals not to exceed 6 months unless a longer interval is granted by specific license condition. If there is reason to suspect that a sealed source might have been damaged, or might be leaking, it shall be tested for leakage before further use.

(2) Leak tests shall be capable of detecting the presence of 5 nanocuries of radioactive material on the test sample or, in the case of radium, the escape of radon at the rate of 1 nanocurie per 24 hours. Any test conducted pursuant to subrule (1) which reveals the presence of 5 nanocuries or more of removable contamination or, in the case of radium, the escape of radon at the rate of 1 nanocurie or more per 24 hours shall be considered evidence that the sealed source is leaking. The licensee shall immediately withdraw the source from use and shall cause it to be decontaminated and repaired or to be disposed of in accordance with applicable provisions of part 5.

(3) Leak test results shall be recorded in units of nanocuries and maintained for inspection as required by rule 245.

[Note: As a result of Executive Order 1996-1, the authority, powers, duties, functions, and responsibilities of the radioactive material registration, licensing, and compliance program were transferred from the Michigan Department of Public Health to the Michigan Department of Environmental.]

R325.5465. Radiation surveys.

Rule 465. (1) The maximum exposure rate at a distance of 1 meter from each patient in whom brachytherapy sources have been inserted, shall be determined immediately after administration of the material, either by measurement or calculation and preferably by both. This exposure rate shall be entered on the patient's chart and other signs as required in rule 466.

(2) The patient's room and surrounding area shall be surveyed upon initiation of treatment in order to assure that the requirements of rule 468 are met. Calculations based upon previous surveys will comply with this subrule. Survey results or calculations shall be recorded on Form RH-104 or equivalent and maintained for inspection as required by rule 245.

[Note: As a result of Executive Order 1996-1, the authority, powers, duties, functions, and responsibilities of the radioactive material registration, licensing, and compliance program were transferred from the Michigan Department of Public Health to the Michigan Department of Environmental Quality. Form RH-104 has been renamed EQP-1612.]

R325.5466. Signs and records.

Rule 466. (1) In addition to the requirements of rules 224 to 231, the bed, cubicle or room of the hospital brachytherapy patient shall be marked with a tag or sign indicating the presence of brachytherapy sources. This

sign shall incorporate the radiation symbol and specify the radionuclide, the activity, date, and the individuals to contact for radiation safety instructions.

(2) A "Radioactivity Precautions" tag or sign shall be attached to the patient's chart or equivalent information incorporated in the chart. The tag shall bear the radiation symbol and include the following information:

(a) The radionuclide administered, number of sources, activity in millicuries and time and date of administration.
(b) The exposure rate at 1 meter, the time the determination was made, and by whom.
(c) The date on which precautions shall cease to be required and on which the tag required under subrule (1) may be removed.
(d) The precautionary instructions necessary to assure that the exposure to individuals other than the patient does not exceed that permitted under rules 203, 205 and 468.

(3) Upon termination of treatment the person removing the sealed sources shall indicate the radiation safety status, date, time and his signature on a distinctively colored form as follows:

CERTIFICATION OF RADIATION HAZARD STATUS:

At _____ a.m./p.m. on _____ (date) the brachytherapy treatment of this patient was terminated and the source(s) of radiation removed. Further radiation safety precautions are no longer required in connection with this patient.

(signature)

Only after this certification has been placed in the patient's file shall the sign required by subrule (1) be removed from the patient's room.

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R325.5468. Radiation dose control.

Rule 468. (1) As required in rules 203 and 205 the radiation dose of visitors, the occasionally exposed, and other individuals not classified as occupational radiation workers shall be limited to less than 0.5 rem per year.

(2) In order to meet the individual dose limits, as provided in rules 203 and 205, radiation protection control shall limit the dose of patients not receiving therapeutic radiation to 200 mrem per admission. The dose limit of 200 mrem to "non-radioactive patients" shall be used for planning radiation protection control and doses up to 0.5 rem per admission may be authorized by the radiation protection supervisor on an individual case basis under conditions of emergency.

(3) Control shall be exercised by the licensee or applicant to assure that the dose of visitors and hospital staff does not exceed the limits given in rules 203 and 205. In general, visitors should remain about 1.8 meters (6 feet) or more from the patient, except for brief periods to shake hands, deliver mail, and the like. Pregnant women and children shall not in general be allowed to visit patients having an appreciable radioactive burden. Exceptions can be made in case of urgency, but the visits should be brief, a distance of 6 feet or more shall be maintained, and written authorization by the radiation protection supervisor shall be required. The control measures exercised may appropriately include the use of personnel monitoring devices by visitors, hospital staff and others.

(4) Female personnel known to be pregnant shall not attend the brachytherapy patient during radiation treatment.

(5) Nursing personnel attending the brachytherapy patient shall be considered radiation workers and shall be assigned individual personnel monitoring equipment. If the brachytherapy workload does not justify permanent dosimeter assignment to each nurse, additional dosimeters may be ordered as needed, if they are individually assigned during the monitoring period and the name of the individual to whom each dosimeter is assigned is transcribed to the permanent dosimeter dose record.

[Note: As a result of Executive Order 1996-1, the authority, powers, duties, functions, and responsibilities of the radioactive material registration, licensing, and compliance program were transferred from the Michigan Department of Public Health to the Michigan Department of Environmental Quality.]

TELETHERAPY

R325.5471. Equipment.

Rule 471. (1) The housing of teletherapy equipment shall be so constructed that, at 1 meter from the source, the maximum exposure rate does not exceed 10 milliroentgens per hour when the beam control mechanism is in the "off" position. The average exposure rate measured at a representative number of points about the housing, each 1 meter from the source, shall not exceed 2 milliroentgens per hour.

(2) For teletherapy equipment manufactured after the effective date of these rules, the leakage radiation measured at one meter from the source when the beam control mechanism is in the "on" position shall not exceed 1 roentgen per hour or 0.1% of the useful beam exposure rate.

(3) Adjustable or removable beam-defining diaphragms shall allow transmission of not more than 5% of the useful beam exposure rate.

(4) The beam control mechanism shall be of a positive design capable of acting in any orientation of the housing for which it is designed to be used. In addition to an automatic closing device, the mechanism shall be designed so that it can be manually returned to the "off" position with a minimum risk of exposure.

(5) The closing device shall be so designed as to return automatically to the "off" position in the event of any breakdown or interruption of the activating force and shall stay in the "off" position until activated from the control panel.

(6) When any door to the treatment room is opened, the beam control mechanism shall automatically and rapidly restore the unit to the "off" position and cause it to remain there until the unit is reactivated from the control panel.

(7) There shall be at the housing and at the control panel a visible warning device that plainly indicates whether the beam is on or off.

(8) The equipment shall be provided with a locking device to prevent unauthorized use.

(9) A suitable exposure control device such as an automatic timer, exposure meter or dose meter shall be provided to terminate the exposure after a preset time interval or preset exposure or dose limit. It shall be designed to preserve its cumulated response in the event of equipment failure during patient treatment. If a timer is used, it shall permit accurate resetting and determination of exposure times as short as 1 second. Means shall be provided for the operator to terminate the exposure at any time.

(10) Provisions shall be made to permit continuous observation of patients during irradiation.

[Note: As a result of Executive Order 1996-1, the authority, powers, duties, functions, and responsibilities of the radioactive material registration, licensing, and compliance program were transferred from the Michigan Department of Public Health to the Michigan Department of Environmental Quality.]

R325.5474. Conditions of operation.

Rule 474. The equipment shall be locked when unattended to prevent unauthorized use.

[Note: As a result of Executive Order 1996-1, the authority, powers, duties, functions, and responsibilities of the radioactive material registration, licensing, and compliance program were transferred from the Michigan Department of Public Health to the Michigan Department of Environmental Quality.]

R325.5475. Testing for leakage and contamination.

Rule 475. Teletherapy sources shall be tested for leakage and contamination in accordance with the procedures described in rule 464, except that leak tests shall be capable of detecting 50 nanocuries of removable contamination, and a source shall be considered to be leaking if the test reveals the presence of 50 nanocuries or more of removable contamination. Tests of leakage may be made by wiping accessible surfaces of the housing port or collimator while the source is in the "off" position and measuring these wipes for transferred contamination.

[Note: As a result of Executive Order 1996-1, the authority, powers, duties, functions, and responsibilities of the radioactive material registration, licensing, and compliance program were transferred from the Michigan Department of Public Health to the Michigan Department of Environmental Quality.]